REMARKS/ARGUMENTS

Claims 11, 14, 15, 16, 19, and 21-25 are pending, claims 1-10, 12-13, 17-18, 20, and 26-57 having been canceled. Support for the amendment to claim 11 is provided by *e.g.*, p. 51, lines 19-22 (treating of patients suffering from the disorder) and previous claim 16. These amendments should not be construed as an acquiescence in any ground of rejection. The dependencies of claims 14, 15, and 21 have been amended so that they depend from pending claims.

¶2. The restriction requirement is moot in view of claim amendments.

¶¶11-27. The Examiner agrees that the specification is enabling for a "method of treating a prion disorder in a mammalian subject, comprising administering to the subject a dosage of an amyloid component derived from a prion precursor protein (PrP) including genetic variants of the PrP associated with hereditary amyloidosis effective to produce an immune response comprising antibodies against said amyloid component and an adjuvant that augments the immune response to said amyloid component." However, the Examiner alleges the specification is not enabling for prevention of a prion-based disorder in a mammalian subject using said method or other agents.

In response, applicants have amended the claim to specify a method of treating a patient suffering from a prion-based disorder, and that the agent is PrP or AScr. It is believed that the Examiner agrees that this subject matter is enabled, and therefore applicants have not responded to the Examiner's comments concerning enablement of other subject matter. This amendment is made to speed allowance of the current claims. Applicants intend to pursue claims of broader scope in related cases.

¶28. Obviousness-Type Double Patenting

The instant Office Action maintains the rejection of claims 11-25 under provisional obvious-type non-statutory doubling patenting as set forth at pages 12-14, ¶¶26-33 of the Office Action mailed December 4, 2002 (Paper No. 14), *i.e.*, U.S. Application Nos. 09/723,927 (claims 44-45, 48, and 67-88); 09/724,489 (claims 67-101); 09/723,760 (claims 38,

40, 42-52, 56-59); 09/724,940 (claims 31-58); 09/724,921 (claims 1-2, 7, 10-11, 14-25); 09/724,929 (claims 1-2, 7, 10-11, and 14-25); 09/979,701 (claims 48-84); 09/723,544 (claims 79-81); 09/723,765 (claims 1-6, 8-9, 11-28); 09/724,291 (claims 1-6, 8-9, 11-28); 09/204,838 (claims 1-2, 7, 17, 20, and 26-31); 09/723,725 (claims 39-42); 09/980,568 (claims 90-97); and, 09/579,690 (claim 27); and, U.S. Patent No. 5,780,587 taken with International Publication No. WO 00/06554.

The Examiner has failed to establish a *prima facie* case of provisional obviousness-type double patenting for the foregoing cases. The analysis involved in a double patenting type determination parallels the guidelines for a 35 U.S.C. § 103(a) rejection set forth in *Graham v. John Deere Co.*, 148 USPQ 459 (1966). To establish a *prima facie* of obviousness the Examiner must make clear (1) the differences between the inventions defined by the conflicting claims; and, (2) the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claims pending in the instant application are an obvious variation of the invention claims in the foregoing applications (*see* p. 800-22, § 804 of the MPEP 8th ed., Rev. 1, February 2003). A statement of rejection must explain with reasonable specificity the basis of the rejection, other wise the Examiner fails to establish a *prima facie* case of obviousness. *Ex parte Blanc*, 13 USPQ2d 1383 (BD. Pat. App. & Intf. 1989). Claims 12, 13, 17, 18, and 20 have of the instant application have been canceled thereby mooting the rejection as to those claims.

The Examiner has failed the explain the rejections with reasonable specificity. Here, it is respectfully submitted that the Examiner has merely summarized the content of only some of the cited cases and then added a conclusory statement that the person of skill in the art would have been motivated to make "the modifications" (*see* ¶3, p. 13-14 of the Office Action mailed December 4, 2002). However, the Examiner fails to state what modifications would need to be made. Applicant respectfully suggests that the Examiner could not explain the rejection with reasonable specificity because he failed to consider the presently claimed invention. For example, the Examiner, citing Jen *et al.*, states that it would have been obvious to the person of ordinary skill in the art at the time the invention was made to use a fragment of Aβ because amyloid β protein precursor (β-APP and fragments thereof are immunogenic) (*see* ¶32, p. 13 of

the Office Action mailed December 4, 2002). (Emphasis added.) However, the instant claims are not directed to the use of a fragment of Aβ, instead, they are directed to administering a dosage of PrP including genetic variants of the PrP associated with hereditary amyloidosis or AScr. Further, it appears that the Examiner believes that claims 11-25 are directed to treating Alzheimer's disease when, in fact, the claims 11-25 are directed to treating a prion disorder.

The has Examiner failed to make the differences between the inventions defined by the conflicting claims clear. The Examiner states that claims 11-25 are rejected because the disclosures of the cited cases meet the limitations of claims 11-25 (*see* ¶¶29-31, pgs 12-13 of the Office Action mailed December 4, 2002). Applicant disagrees and respectfully points out that the Examiner has made an obviousness rejection but is applying a novelty standard. Determining that disclosures of the cited cases meet the limitations of claims 11-25 is not relevant to an obviousness-type double patenting determination. As discussed above, the Examiner must determine the difference between the inventions defined by the conflicting claims. Here, the Examiner has failed to make such a determination. Lastly, none of cited claims recite administering a dosage of PrP including genetic variants of the PrP associated with hereditary amyloidosis or AScr as do claims 11-25. Thus, the cited claims do not meet the limitations of claims 11-25.

Based on the foregoing, Applicant respectfully requests the withdrawal of the provisional obviousness-type double patenting rejections.

¶29. Claims 11, 14, 15 and 16 stand rejected as anticipated by Prusiner, PNAS. Prusiner is said to teach immunization of Prn-$P^{0/0}$ mice with scrapie prion proteins in Freund's adjuvant to produce antibodies. This rejection is respectfully traversed, particularly as applied to the amended claims.

The PrP-$P^{0/0}$ strain of mice is a genetically modified strain of mice that does not develop prion based disease (*see* first sentence of Abstract). Accordingly, such a mouse does not constitute a patient suffering from a prion-based disorder as required by the amended claims. Therefore, there is no anticipation.

The PrP-$P^{0/0}$ mice were administered AScr simply as a means of producing antibodies to AScr (*see* p. 10611, first column, ¶2). There is no suggestion that administering the antibodies has any therapuetic benefit. Accordingly, the reference does not suggest administering PrP or AScr to a patient suffering from a prion-based disorder. Therefore, the claims would not have been obvious from the reference.

¶30. Claims 11, 14, 15 and 16 stand rejected as anticipated by Prusiner, WO 97/10505. The reference is alleged to teach production of antibodies by immunization of a host mammal with infectious PrP^{Sc} together with incomplete Freund's adjuvant (citing to pp. 22-23).

The amended claims are distinguished from this reference for essentially the same reasons as Prusiner, PNAS. Prusiner, WO 97/10505 does not disclose administering PrP^{Sc} to an animal suffering from a prion-based disorder. It appears the mammals used by Prusiner were normal healthy animals. Prusiner also administers PrP^{Sc} to an animal simply for the purpose of generating antibodies and does not suggest any therapeutic benefit. Therefore, the amended claims are not anticipated by or obvious over Prusiner, WO 97/10505 either.

¶31. Claims 11, 14, 15 and 16 stand rejected under 35 USC 102(e) as anticipated by Prusiner, US 2001/0021769 (citing to paragraph 49, 50, and 89-91).

This rejection is respectfully traversed, particularly as applied to the amended claims, for at least the same reasons as the other two Prusiner references. Paragraphs 49 and 50 refer generally to antibodies to PrP^{Sc} but do not describe how they are generated, much less immunization of an animal suffering from a prion based disorder. Paragraphs 89-91 discuss producing antibodies to Her-2/neu and do not appear to be relevant. In any event, Prusiner, US 2001/0021769 does not disclose or suggest immunizing a mammal suffering from a prion-based disorder. For these reasons, withdrawal of the rejection is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

Rosemarie L. Celli

Rosemarie L. Celli
Reg. No. 42,397

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 650-326-2400
Fax: 650-326-2422
Attachments (as noted)
RLC:lah
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